



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Applicant : Jesse John Kiefer et al.
Serial No. : 10/047,967
Filed : January 16, 2002
For : CENTERFILLED CHEWING GUM
CONTAINING A DELIVERABLE FORM OF
CALCIUM
Examiner : Arthur L. Corbin
Art Unit : 1761
Confirmation No. : 3892
Attorney Docket No. : A71-07LAV

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: MAIL STOP AF, COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON D.C. 20231

ON December 21, 2005

NAME Jill S. Garretson

SIGNATURE *Jill S. Garretson*

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

December 21, 2005

DECLARATION

Dear Sir:

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I, Jesse John Kiefer, declare and say as follows:

1. I am one of the inventors of the subject matter of the above-identified patent application.

2. I am fully familiar with the prosecution history of the above-identified patent application and those references which have been cited as part of the prior art including Bell et al. (WO 00/06127) and Cherukuri et al. (U.S. Patent No. 4,352,823).

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3. I am aware that the claims of the present application have been rejected as obvious over Bell et al. alone or in combination with Cherukuri et al.

4. The present invention is directed to a chewing gum composition which has as its object to deliver an effective amount of calcium to the user by chewing a reasonable number of pieces of chewing gum per day. A reasonable number of pieces is from 3 to 5.

5. Chewing gum products can be comprised of a single, blended mixture or they can be comprised of layers or areas of single ingredients or layers of mixtures. Chewing gum product layers can include chewing gum compositions comprised of water insoluble components and water soluble components. Additionally, the layers can include coatings that form an outer surface comprised of single ingredients or mixtures of ingredients such as saccharides, fats, proteins, shellacs, waxes, etc. Furthermore, the layers can include compositions that do not form an outer surface and that when taken alone would not be perceived as chewing gum. These non-outer surface layers can form the center of a chewing gum product and can include saccharides, hydrocolloids, polyols, fats, emulsifiers, etc.

6. Chewing gum products can include active ingredients. These active ingredients offer benefits to the consumer such as therapeutic benefits. These actives can be included in the mixture of a single, blended mixture chewing gum format, or they can be included in any of the layers that may be present in a chewing gum composition. It is essential that the active ingredient be released in a manner which provides an effective amount of the ingredient to the user to achieve a benefit. How the active is included in the chewing gum product depends on considerations such as desired release profile for the active, compatibility of the active with other components of the mixture or layer, and solubility of the active in aqueous systems.

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7. One type of active that has been considered for chewing gum is mineral salts. Mineral salts when properly present in the chewing gum can provide a nutritionally fortified product. When selecting a mineral salt to fortify a chewing gum, the water solubility, mineral content, and taste of the mineral salt must be considered. Because chewing gum has a small serving size, an important consideration is mineral content driven by the need to use a salt with the highest mineral content possible. For calcium fortification, using a calcium salt with a high calcium content can result in a finished product offering an effective dose of calcium delivered through a reasonable number of pieces of chewing gum. Calcium carbonate has a calcium content of 40% making it a good example of an attractive option for fortification. However, calcium carbonate is water insoluble and therefore has an affinity for the water insoluble portion of the chewing gum base. The water insoluble portion includes styrene butadiene rubber, polyisobutylene, butyl rubber, waxes, fats, and resins.

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8. One of the major draw backs of non-water soluble and sparingly water soluble calcium-containing compounds such as calcium carbonate is that they have a high affinity for the gum base. Such calcium compounds therefore become trapped within the gum base and are not effectively released therefrom. Even if one
5 were to add more calcium compound to compensate for the inefficiency of calcium release, the sensory and taste properties of the chewing gum composition are often adversely affected.

9. The present invention therefore has focused on a centerfill chewing
10 gum composition in which the centerfill contains no gum base. I have observed the examples appearing in the present application beginning on page 16 and confirm that they are consistent with the disclosure of the present invention. In particular, it is noted that the centerfills of the examples contain a calcium-containing compound (e.g. calcium carbonate) but no gum base. Gum bases are only contained outside
15 of the centerfill portion. The purpose of eliminating gum base from the centerfill portion is to provide an environment in which the calcium-containing compound which is non-water soluble or only sparingly water soluble can be housed without concern for it being trapped within the gum base. As indicated above, the centerfill must be free of gum base.

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10. Thus, in order to use calcium carbonate for fortification such that it will not become bound up in the water insoluble portion of the chewing gum, it must be included in areas of the gum composition that do not contain water insoluble components. Similarly, other insoluble or sparingly soluble calcium salts such as

calcium phosphate could be used as long as they are similarly included in areas in which water insoluble components are absent. An area that does not contain water insoluble components can be an aqueous center fill.

5 11. However, placement of calcium-containing compounds in a gum base free centerfill portion still does not provide effective release of the calcium so that an effective amount of the calcium may be provided to the oral cavity. We have discovered that it is necessary to ensure that the calcium-containing compounds are effectively suspended and dispersed throughout the centerfill portion. This provides
10 a relatively high solids content and therefore effective delivery of the calcium without adversely effecting the viscosity of the center-fill to a point where the taste and/or sensory characteristics of the chewing gum composition are compromised.

 12. Because calcium salts with high calcium contents tend to be insoluble
15 or sparingly soluble, the problem of settling must be addressed when they are included in an aqueous center fill. Settling can cause consumers to perceive the chewing gum as being gritty. Settling can also reduce the amount of the calcium compound that is released during chewing. Hydrocolloids are commonly used in aqueous center fillings due to their ability to increase the viscosity of the aqueous
20 phase thereby reducing the potential for settling of the solids dispersed therein. Polyols such as glycerine can also be used. However, hydrocolloids and/or polyols alone cannot eliminate settling. Settling can be managed in conjunction with viscosity management by limiting the calcium-containing compound to an appropriate particle size distribution.

Thus, to effectively formulate a chewing gum product offering mineral salt fortification, a mineral salt with a high mineral content should be used even though the low solubility of such a mineral salt will preclude its inclusion in layers of the product containing water insoluble components. Aqueous center fill layers offer a vehicle for low solubility mineral salt incorporation into chewing gums, but the problem of settling must be addressed. We found that managing the viscosity of the center fill and the particle size distribution of the mineral salt resulted in a uniform dispersion that did not settle out.

13. We have therefore focused on using a very small average size particle distribution for the calcium-containing compound. We have discovered that an average particle size for the calcium-containing compound of less than about 17 microns is important to provide the suspension and uniform dispersion characteristics necessary to provide effective calcium release and to eliminate the problem of settling.

14. Calcium carbonate is a known filler for chewing gum base. Fillers in chewing gum provides texture to the gum base. The water insolubility of calcium carbonate is an advantage when calcium carbonate functions as a filler because calcium carbonate does not release from the gum base and enables it to provide a texturizing effect throughout the chew period. Thus, the water insolubility of calcium carbonate that makes it an effective filler when used to texturize the gum base renders it ineffective when it is desired to have the calcium carbonate released from

the gum base to function as a calcium supplement. It should be noted that calcium carbonate when used as a filler for the gum base can be incorporated into the gum base regardless of where the gum base is located whether it be in the shell or core portion of a centerfill chewing gum composition.

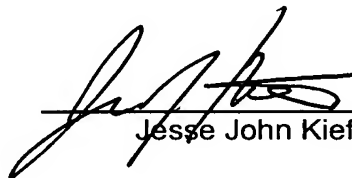
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15. I have been advised that during the prosecution history of the above-identified application, Cherukuri et al. has been cited as disclosing a centerfill chewing gum composition in which the centerfill is free of gum base. This, however, is not correct. The reference discloses a soft core portion which includes a non-
10 styrene-butadiene gum base as disclosed in the reference at column 2, lines 45-62. The calcium carbonate present as a filler-texturizing agent will therefore be trapped in the gum base making it unavailable to serve as a calcium supplement (see paragraphs 8 and 9 herein).

15 I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false
20 statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 12/5/05

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Jesse John Kiefer

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